

FEB 13 2014

005_PALS_510K_Summary_2_5_2014

 K132422
510(k) Summary
 807.92(c)

Submitter/Contact Person

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Device Identification

 Common Name: Electrodes, Cutaneous
 Trade Name/Common Name: PALS® Neurostimulation Electrodes
 Regulation No.: 21CFR 882.1320 Electrodes, Cutaneous
 Classification: Class II
 Product Code: GXY

Device Description (807.92[a] [4])

The Axelgaard PALS® Neurostimulation reusable self-adhering electrode is used as a transcutaneous electrical nerve stimulation electrode in conjunction with an electrical stimulator for TENS or EMS.

Technical Characteristics

The device functions as a passive device by carrying an electrical signal from a neurostimulation device through the device cable and electrode lead wire to the user skin. It is composed of a cover, connector lead wire, stretchable conductive fabric, conductive hydrogel, and an electrode carrier liner. Proper current distribution is delivered via a connector lead wire stripped to an additional length.

Axelgaard Manufacturing manufactures the PALS® Neurostimulation Over the Counter Electrode and the ValuTrode Over the Counter Neurostimulation Electrodes (K13987) with the same conductive hydrogel, and electrode carrier.

Everyway Medical manufactures the Lifecare Electrode (K083302) with the same conductive hydrogel and conductive carbon film as Axelgaard's ValuTrode Neurostimulation Electrodes (K130987). Axelgaard Manufacturing supplies these components to Everyway.

Intended Use (807.92[a] [5])

PALS® reusable, self-adhering, over-the-counter Neurostimulation Electrodes are indicated for use with transcutaneous electrical stimulation devices. Some common types of transcutaneous stimulation devices include, but are not limited to, transepithelial nerve stimulation (TENS) and electrical muscle stimulation (EMS) devices. Transcutaneous Neurostimulation Electrodes are passive devices serving as an interface between a user's skin and a neurostimulation device.

Legally Marketed Predicate Devices (807.92[a] [3])

Device Name	Manufacturer	510(k) No.	Date Cleared
PALS® Flex Neurostimulation Electrodes	Axelgaard Manufacturing Co., Ltd.	K874469	1998
Life Care Electrodes	Everyway Medical Instruments Co.	K083302	2009
ValuTrode® Neurostimulation Over the Counter Electrodes	Axelgaard Manufacturing Co., Ltd.	K130987	2013

(The Substantial Equivalency Summary and subsequent pages are formatted in landscape orientation for ease of reading.)

Substantial Equivalence Summary (807.92[a] [6])

Subject Device Axelgaard PALS® Neurostimulation OTC	Axelgaard PALS Flex (K874469)	Everyway Lifecare (K083302)	Axelgaard ValuTrode OTC (K130987)
Technology <p>Cutaneous electrode which conducts an electrical signal from a neurostimulation device through a leadwire; which is dispersed from the leadwire across a stretchable conductive fabric then transmitted through the conductive adhesive gel to the surface of the user's skin.</p>	<p>Cutaneous electrode which conducts an electrical signal from a neurostimulation device through a leadwire; which is dispersed from the leadwire/snap across a conductive surface; then transmitted through the conductive adhesive gel to the surface of the user's skin.</p> <p>Safety & Effectiveness: Based on successful biocompatibility testing of the skin contacting conductive hydrogel, the electrical performance of the insulated leadwire components and electrode current distribution test results, the PALS® Neurostimulation devices are safe and effective when used as an interface between a user's skin and an approved neurostimulation devices.</p> <p>Our labeling indicates consulting the stimulator manual for proper electrode size and placement. Do not exceed 0.1 watts/cm².</p>	<p>Cutaneous electrode which conducts an electrical signal from a neurostimulation device through a leadwire; which is dispersed from the leadwire/snap across a conductive surface; then transmitted through the conductive adhesive gel to the surface of the user's skin. The electrode connection point (leadwire) is compatible with standard, marketed Neurostimulation devices. The device is safe and effective as the predicate devices cited (within their 510(k) submittal).</p> <p>Safety & Effectiveness: Based on successful biocompatibility testing of the skin contacting conductive hydrogel, the electrical performance of the insulated leadwire components and electrode current distribution test results, the PALS® Flex neurostimulation devices are safe and effective when used as an interface between a user's skin and an approved neurostimulation devices.</p> <p>Our labeling states: "Consult stimulator manual for proper electrode size. Do not exceed 0.1 watts/cm²".</p>	<p>Cutaneous electrode which conducts an electrical signal from a neurostimulation device through a leadwire (or snap); which is dispersed from the leadwire/snap across a conductive surface; then transmitted through the conductive adhesive gel to the surface of the user's skin.</p> <p>Safety & Effectiveness: Based on successful biocompatibility testing of the skin contacting conductive hydrogel, the electrical performance of the snap / insulated leadwire components and electrode current distribution test results, the ValuTrode neurostimulation devices are safe and effective when used as an interface between a user's skin and an approved neurostimulation devices.</p> <p>Our labeling indicates consulting the stimulator manual for proper electrode size and placement. Do not exceed 0.1 watts/cm².</p> <p>FDA max power guidelines draft guidance 2010 states in Section D.(vi) a maximum average power density that does not exceed .025 watts per square centimeter of electrode conductive surface area.</p> <p>FDA max power guidelines draft guidance 2010 states in Section D.(vi) a maximum average power density that does not exceed .025 watts per square centimeter of electrode conductive surface area.</p>

Subject Device	Axelgaard PALS® Neurostimulation OTC	Everyway Lifecare (K0833302)	Axelgaard ValuTrode OTC (K130987)
Features / Materials	<p>Four basic components:</p> <ul style="list-style-type: none"> Top cover material Lead wire connection <ul style="list-style-type: none"> Lead wire has insulation on female connector Stretchable conductive fabric Conductive hydrogel 	<p>Four basic components:</p> <ul style="list-style-type: none"> Top cover material Lead wire connection <ul style="list-style-type: none"> Lead wire has insulation on female connector Conductive carbon film Conductive hydrogel 	<p>Four basic components:</p> <ul style="list-style-type: none"> Top cover material Lead wire or snap connection <ul style="list-style-type: none"> Lead wire has insulation on female connector Conductive carbon film Conductive hydrogel
Indications of Use Principles of Operation	<p>PALS® reusable, self-adhering, over-the-counter Neurostimulation</p> <p>Electrodes are indicated for use with transcutaneous electrical stimulation devices.</p> <p>Some common types of transcutaneous stimulation devices include, but are not limited to, transepithelial nerve stimulation (TENS) and electrical muscle stimulation (EMS) devices.</p> <p>Transcutaneous Neurostimulation</p> <p>Electrodes are passive devices serving as an interface between a user's skin and a neurostimulation device.</p>	<p>The Axelgaard PALS® Flex electrode is a reusable disposable device which adheres to the patient over the entire surface of the electrode. The device is intended to be used in connection with any neurostimulation approved for distribution within the USA.</p>	<p>Electrodes are intended for use with transcutaneous neurostimulation devices as over the counter devices.</p> <p>Some common type of neurostimulation devices include, but are not limited to, TENS and EMS devices.</p> <p>Transcutaneous neurostimulation electrodes are passive devices serving as an interface between a patient's skin and a neurostimulation device.</p>
Differences	<p>PALS® Neurostimulation electrodes will offer lead wire connection configurations.</p> <p>PALS® electrodes utilize a stretchable conductive fabric.</p> <p>We claim that these electrodes can be sold as OTC (over-the-counter) under the 510(k) regulation (21 CFR 801 Subpart C) requiring 510(k) submittal.</p>	<p>PALS® Flex electrodes offer lead wire connection configurations</p> <p>PALS® Flex electrodes utilize a stretchable conductive fabric.</p> <p>The devices are sold as prescription only devices.</p>	<p>The Lifecare Electrode 510(k) only offers lead wire connection electrodes.</p> <p>Lifecare Electrodes utilize conductive film.</p> <p>Lifecare Electrodes are sold as over-the-counter devices.</p>
			<p>ValuTrode® over the counter electrodes offer lead wire and snap connection configurations.</p> <p>Axelgaard ValuTrode® electrodes utilize conductive film.</p> <p>The devices are sold as over-the-counter devices.</p>

Performance Data

No performance data is required to support this submission since the proposed over-the-counter PALS® Neurostimulation Electrode has identical technological characteristics (including design) as compared to the currently marketed predicate PALS Flex Electrodes (K874469) and ValuTrode® Over the Counter Electrodes (K130987). This pre-market notification supports a change only to allow the product to be sold for over-the-counter use.

Safety / Effectiveness and Conclusion Statement (860.7)

Axelgaard Manufacturing Co., Ltd. considers the PALS® over-the-counter Neurostimulation electrode to be as safe and effective as the predicated devices PALS Flex (K874469) and ValuTrode OTC (K130987) noted above.

Based upon an evaluation of the proposed PALS® electrode, compared with the Lifecare, and ValuTrode® Over the Counter electrodes, Axelgaard Manufacturing Co., Ltd. believes that the proposed PALS® self adhering reusable **Neurostimulation Electrode** is suitable for over-the-counter under the 510(k) regulation (21 CFR 801 Subpart C) requiring 510(k) submittal.



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

February 13, 2014

Axelgaard Manufacturing Co., Ltd.

Mr. Dan Jeffery, President

520 Industrial Way

Fallbrook, CA 92028

Re: K132422

Trade/Device Name: PALS® Neurostimulation Electrodes

Regulation Number: 21 CFR 882.1320

Regulation Name: Cutaneous Electrodes

Regulatory Class: Class II

Product Code: GXY

Dated: November 18, 2013

Received: November 19, 2013

Dear Mr. Jeffery:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA).

You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Joyce M. Whang -S

for Carlos Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number (if known)

K132422

Device Name

PALS® Neurostimulation Electrodes

Indications for Use (Describe)

PALS® reusable, self-adhering, over-the-counter Neurostimulation Electrodes are indicated for use with transcutaneous electrical stimulation devices. Some common types of transcutaneous stimulation devices include, but are not limited to, transepithelial nerve stimulation (TENS) and electrical muscle stimulation (EMS) devices. Transcutaneous Neurostimulation Electrodes are passive devices serving as an interface between a user's skin and a neurostimulation device.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D) Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

Joyce M. Whang -S

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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